

REMARKS

Claims 1-9 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Vaska '605. This rejection is respectfully traversed.

Claim 1 specifically recites “advancing a surgical instrument through the opening in the pericardium near the apex region and along a path lateral to the left pulmonary veins into the transverse pericardial sinus; forming an opening in a first reflection disposed between the left and right superior pulmonary veins”; and “form an opening in a second reflection disposed between the superior vena cava and the right superior pulmonary vein; advancing the surgical instrument through the opening formed in the second reflection”; and “forming an opening in a third reflection disposed between the inferior vena cava and the right inferior pulmonary vein; advancing the surgical instrument through the opening formed in the third reflection into the oblique pericardial sinus to substantially surround the left and right pulmonary veins with the surgical instrument.”

These aspects of the claimed invention establish openings through the reflections through which a surgical instrument can pass or penetrate to substantially surround the left and right pulmonary veins.

These aspects of the claimed invention are not disclosed or even suggested by Vaska '605. Vaska '605 discloses merely “electrically isolate[ing] the pulmonary veins from the surrounding myocardium *without cutting or penetrating*

the pericardial reflections.” Vaska, Abstract (emphasis added). At best, Vaska ’605 merely positions ablation instruments along diverse paths to avoid traversing or penetrating pericardial reflections. There is therefore no disclosure of the sequence, as claimed by Applicant, for *penetrating* pericardial reflections to attain access through openings therein for forming subsequent openings in other pericardial reflections.

In fact, Vaska ’605 *teaches away* from the methods of the claimed invention, advising against “risky and difficult” cutting or puncturing of the pericardial reflections. *See, e.g.,* Vaska, col. 2, ll. 34-38; col. 10, ll. 11-19. As a result, the modification of Vaska ’605 suggested by the Examiner to introduce cutting or penetrating the pericardial reflections would impermissibly change the principle of operation of the reference. *See* MPEP 2143.01 VI. Further, such a modification would take the methods of Vaska ’605 beyond its “established functions,” thus precluding the “predictability” of such a modification. *See KSR*, 127 S.Ct. 1727, 1739 (2007).

In the Advisory Action dated June 4, 2008, the Examiner alleges in her rationale for why the previous amendment did not condition the application for allowance that Applicant has not shown that certain method steps “are not intrinsic.” However, none of claims 1-9 recites any aspects of the limitations postulated by the Examiner as ostensibly placing the burden “to show that these

method steps are not intrinsic” on Applicant, since such method steps are not at issue in Applicant’s pending method claims.

While such steps may be inherently involved in entering a patient’s body according to the prior art to perform a surgical procedure on the patient’s heart, Applicant’s claims seek to patent the *differences* over the prior art, including the clearly recited steps in Applicant’s methods claims that find no counterpart in the disclosure of Vaska ’605.

Dependent claims 2-9 are further limited by such various recitations as “incising the anterior rectus sheath and retracting the rectus muscle to expose the posterior rectus sheath; incising the posterior rectus sheath to expose the inferior border of the costal margin; forming a tract through the incisions and the muscular diaphragm into the pleural cavity”; or “forming an opening in one of the first, second and third reflections includes grasping a portion of the reflection; and cutting the grasped portion of the reflection to form an aperture therein,” or “grasping through the opening formed in the first reflection the surgical instrument positioned within the transverse pericardial sinus for manipulating therein the surgical instrument through the opening formed in the second reflection,” or “pulling the grasped surgical instrument through the opening formed in the third reflection into the oblique pericardial sinus to substantially complete a loop of the surgical instrument surrounding the left and right pulmonary veins.”

Thus, for at least the above reasons, Vaska '605 fails to establish even a *prima facie* basis, including all recited method steps, from which a proper determination of obvious may be formed.

Conclusion

In sum, Applicants respectfully submit that claims 1-9, as presented herein, are patentably distinguishable over the cited reference. Therefore, Applicants request reconsideration of the basis for the rejections to these claims and request allowance of them.

In addition, Applicants respectfully invite the Examiner to contact Applicants' representative at the number provided below regarding any remaining issues that may expedite favorable disposition of this application.

Respectfully Submitted,

Date: August 6, 2008

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